

REMARKS

In view of the above amendments, reconsideration of the outstanding office action is respectfully requested.

The rejection of claims 1-6 and 20-24 under 35 U.S.C. §101 for lack of utility is respectfully traversed.

The claims of the above-identified patent application have a specific, substantial and credible asserted utility. As described in the specification as filed the proteins of the present invention have transcriptional regulatory activity (pg. 29, lines 25-30, pg. 15, lines 17-18, pg. 41, line 29-pg. 43, line 32.) . It is the position of the U.S. Patent and Trademark Office ("PTO") that the application has only provided guesses as to the utility. Applicant's respectfully disagree. As explicitly stated on page 15, lines 17-18, "[t]he proteins have transcriptional activation activity".

Accordingly, the specification identifies an asserted utility. Therefore, the PTO must determine if the asserted utility is specific, substantial and credible. (Manual of Patent Examining Procedure ("MPEP") 2107(B)). Only one credible asserted utility is needed to meet the criteria for 35 USC § 101 (MPEP 2107(B)(1)(ii)). Further, an applicant's asserted utility creates a presumption of utility that is sufficient to satisfy the utility requirement of 35 USC § 101 (MPEP 2107.02 III). If the asserted utility is credible, a rejection based of lack of utility is not appropriate (Id.). In fact, "Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical field of the invention or for other general reasons." (MPEP 2107.02 III.A.)

In particular, the application as filed describes the transcriptional regulatory activity of the protein (pg. 29, lines 25-30, pg. 15, lines 17-18, pg. 41, line 29-pg. 43, line 32.) As shown in the example, the *GAL4-TIG-1* expression plasmid showed a

threefold increase in CAT expression when compared to CAT activity of the GAL4 DNA binding domain (pg. 42, lines 11-30). Further, TPA induced K562 cells cotransfected with the CAT reporter construct and the GAL4-TIG-1 expression vector increase CAT expression by 11-14 fold as compared to uninduced cells (pg. 43, lines 1-12; Figure 7C).

In addition, the structure of the protein of the present invention is similar to a co-activator complex that mediates chromatin-directed transcriptional activation (pg. 44, lines 3-13). It is the PTO's position that structural similarity to a known protein does not suggest functional similarity. Applicants disagree. As stated in MPEP 2107.03 II, evidence of structural similarity can be considered in an evaluation of utility. "Such evidence should be given appropriate weight in determining whether one skilled in the art would find the asserted utility credible." (Id.)

Accordingly, because there is no reason to doubt the assertion that the proteins of the present invention have transcriptional regulatory activity and that such proteins have a well-established utility, applicants asserted utility for the present case is sufficient to meet the utility requirement of 35 USC § 101. No further experimentation is necessary to attribute a utility to the claimed proteins. See *Brenner v. Manson*, 383 US 519, 148 USPQ 689 (1966).

With respect to the statement in the Advisory Action dated November 4, 2003 that applicants have not provided a substantial and specific utility, applicants respectfully disagree. As stated above, as explicitly stated on page 15, lines 17-18, of the application as filed, "[t]he proteins have transcriptional activation activity". This asserted utility is specific in identifying a use specific to the subject matter claimed (MPEP 2107.01). Further, a substantial utility (i.e. a "real world" use) is identified. (Id.). Any reasonable use that is identified for the invention that can be viewed as providing a

public benefit should be accepted as a sufficient substantial utility (Id.) In particular, applicants have identified a use for the protein as those which activate transcription. As shown in the present specification, page 41, line 29 - page 44, line 2, cotransfection assays suggest that the TIG-1 protein functions as a transcriptional activating factor. In particular, TPA induced K562 cells cotransfected with the CAT reporter construct and the GAL4-TIG-1 expression vector increased cat gene expression by 11-14 fold.

Accordingly, the rejection of claims 1-7, 13-17 and 23 for lack of utility is improper and should be withdrawn.

In view of the foregoing, Applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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Appendix (Text of Withdrawn Claims Not Included)

1. (Previously amended) An isolated nucleic acid molecule wherein said nucleic acid molecule encodes an amino acid sequence as shown in SEQ ID NO:3.

2. (Previously amended) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid molecule has a nucleotide sequence as shown in SEQ ID NO:1.

3. (Original) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid is deoxyribonucleic acid.

4. (Original) The isolated nucleic acid molecule of claim 3 wherein said deoxyribonucleic acid is cDNA.

5. (Original) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid is ribonucleic acid.

6. (Original) The isolated nucleic acid molecule of claim 5 wherein said ribonucleic acid is mRNA.

7. (Original) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid encodes a transcriptional activity. The expression vector is selected from the group consisting of a plasmid and a virus.

8-12 (Canceled)

13. (Original) A method of decreasing expression of a transcriptional activator protein in a host cell, said method comprising introducing the oligonucleotide of claim 8 into the cell, wherein said oligonucleotide blocks translation of said mRNA so as to decrease expression of said transcriptional activator protein in said host cell.

14. (Original) A cell comprising the nucleic acid molecule of claim 1.

15. (Original) An expression vector comprising the nucleic acid molecule of claim 1.

16. (Original) The expression vector of claim 15 wherein said expression vector is selected from the group consisting of a plasmid and a virus.

17. (Original) A cell comprising the expression vector of claim 15.

18.-22. (Withdrawn)

23. (Original) An isolated nucleic acid molecule encoding a transcriptional activator protein, said nucleic acid molecule encoding a first amino acid sequence having at least 90% amino acid identity to a second amino acid sequence, said second amino acid sequence as shown in SEQ ID NO:3.

24. (Canceled)

25.-36. (Withdrawn)